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(54) **Prosthetic device for relieving prostatic problems**

(57) A prosthetic device for keeping open the lumen of a prostatic urethra comprises a body of a physiologically acceptable, perforated, resilient material that can be deformed into a channel-shaped configuration in which it can be inserted into the urethra. The resilience of the body, together with anchoring formations 16, 18, ensures that the device is held secure and can be left indwelling in the prostatic urethra for keeping it open.

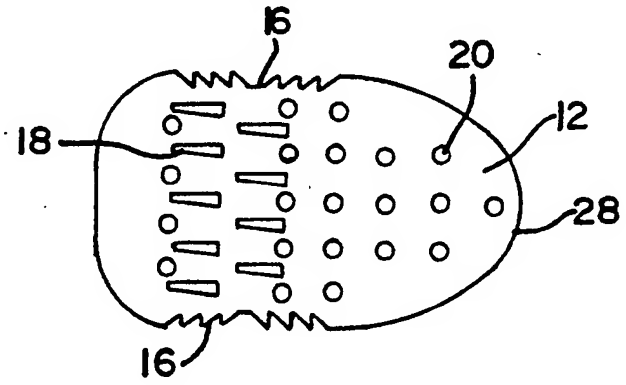

FIG 1

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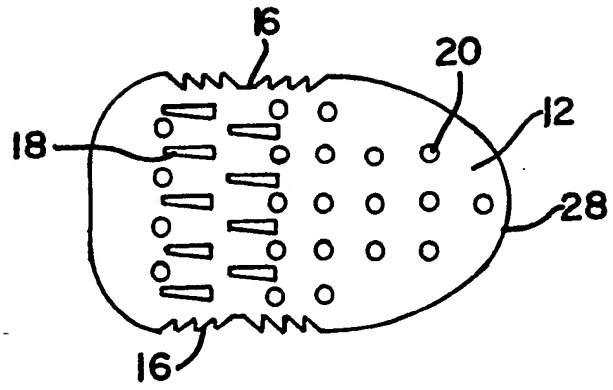

FIG 1

FIG 2

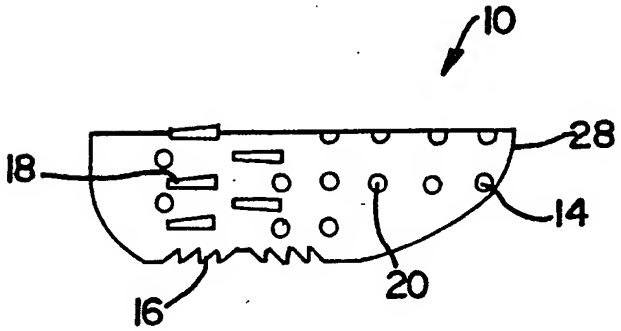

FIG 3

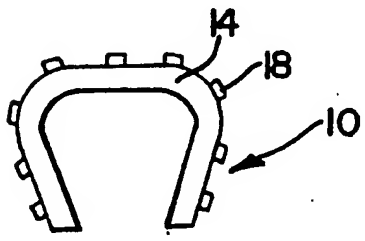

FIG 4

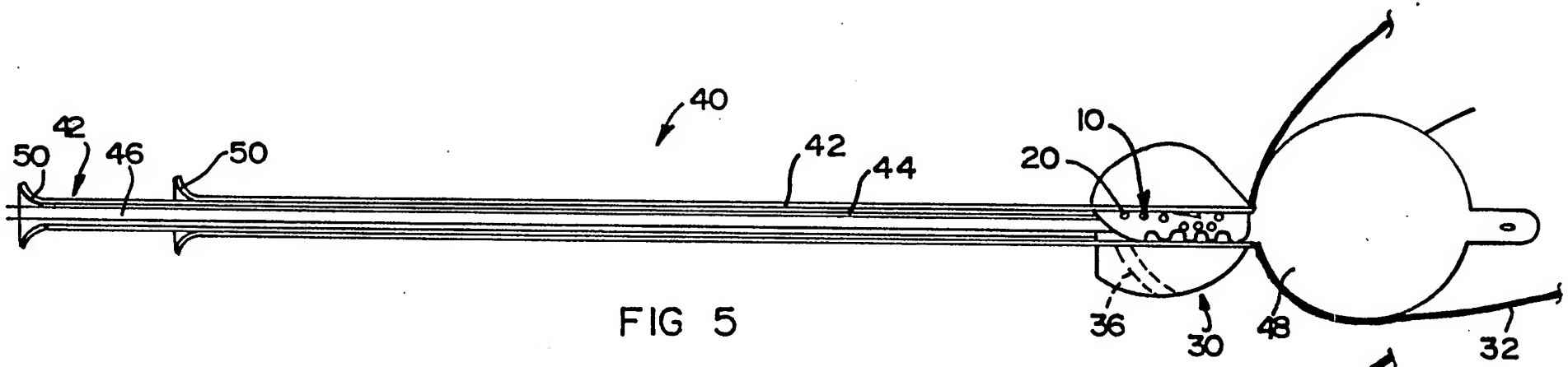

FIG 5

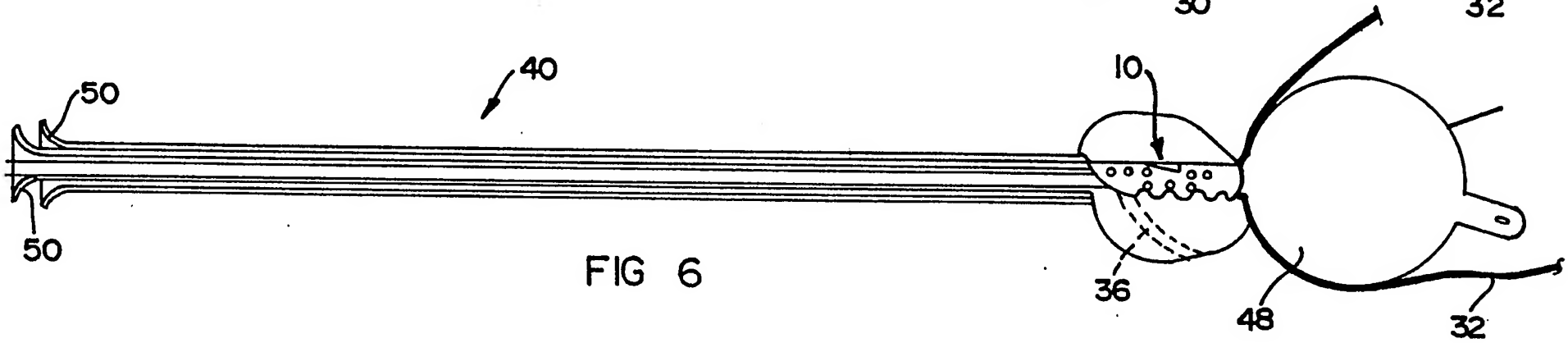

FIG 6

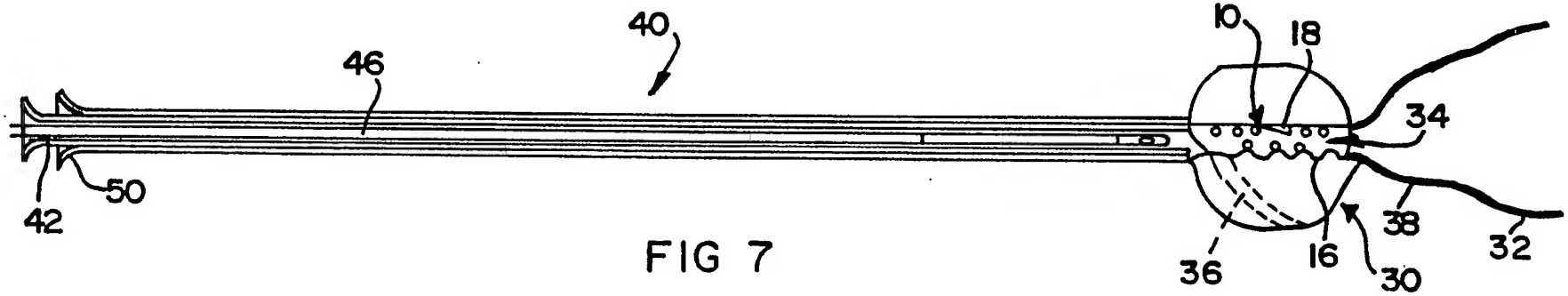

FIG 7

PROSTHETIC DEVICE FOR RELIEVING PROSTATIC PROBLEMS

Hypertrophy of the prostate, and other anomalies associated therewith, is part of the normal ageing process. Enlargement of the prostrate, is likely to put pressure on the prostatic urethra. This may cause stenosis and obstruct micturition. The bladder becomes painfully distended. The resulting urine retention may be relieved by dilatation by the passage of a bougie or a catheter up the urethra. However, this procedure can provide only symptomatic and temporary relief. Repeated catheterisation is required which may often cause traumatisation of the urethra. Eventually a prostatectomy procedure may be required.

According to this invention, a prosthetic device comprises a physiologically acceptable, perforated, resilient body which is channel-shaped in use, the inherent resilience of the body, in its channel-shaped configuration, permitting the lumen of a prostatic urethra being kept open, when the body is left indwelling in the prostatic urethra.

Suitable materials for the device are elastomeric polymers, such as TEFLON(RTM) or silicon elastomers. Also, the body of the device may be lacquered with a coating of a vulcanized silicon elastomer.

The body of the device may be a planar tongue-shaped, resilient element which can be deformed to form its in use channel-shaped configuration. Typically, in use, the channel-shaped body has a horse shoe shaped end profile, the conical portion of the tongue shaped planar element providing a tapered end for the body in its in use channel-shaped configuration.

The channel-shaped body may be provided with anchoring formations. Typically, the edges of the channel-shaped body may be serrated and the surface of the channel-shaped body intended to be in contact with the inner wall of the prostatic urethra may be provided with wedge-shaped projections.

The invention will be understood, more clearly, from the following descriptions taken in conjunction with the accompanying drawings.

In the drawings,

Figure 1 is a plan view of a prosthetic device, in accordance with the invention, in an inoperative configuration;

Figure 2 is a side elevation view of the device as shown in Figure 1;

Figure 3 is side elevation view of the prosthetic device of Figure 1, in an in use, channel-shaped configuration;

Figure 4 is an end elevation view of the device as shown in Figure 3; and

Figures 5 to 7, illustrate in side view the method of implanting the prosthetic device of Figure 1 in the prostatic urethra.

Referring to Figure 3 of the drawings, there is shown a prosthetic device generally indicated by the reference numeral 10. The prosthetic device 10, in use, comprises a resilient,

perforated, channel-shaped body 14 formed by deforming a planar tongue-shaped element as shown in Figure 1.

The body 14 has anchoring formations in the form of serrations 16 along its sides and wedge-shaped projections 18 on the surface of the body which forms the outer surface of the channel-shaped body 14. Also, the body 14 is perforated. The serrations 16 and the wedge shaped projections 18 serve as gripping formations for anchoring the prosthetic device 10 in the prostatic urethra. The channel-shaped body 14 has a horse shoe type end profile in use, as particularly seen in Figure 4, with a tapering end 28, as particularly seen in Figure 3.

The length and other dimensions of the prostatic urethra can be endoscopically determined and these dimensions will determine the dimensions of the prosthetic device 10 and the dimensions of the tongue-shaped planar element forming the body 14.

Preferably, the length of the prosthetic device is such that in its indwelling configuration, it spans the prostatic urethra from the opening (neck) of the bladder right through the prostate, the inherent resilience of its resilient channel-shaped body 14 permitting straddling of the prostatic urethra for maintaining an open lumen.

In the male human body, the vas deference and the seminal vesicle unite to form the ejaculatory duct which traverses the prostate to empty fluids into the prostatic urethra in the verumontanum region. A horse shoe profile has been selected for the channel-shaped body 14 so that an indwelling prosthetic device 10 implanted in the prostatic urethra, does not obstruct the flow of fluid from the ejaculatory duct.

The prostate produces prostatic secretions, which reach the prostatic urethra through a number of little ducts which empty into the prostatic urethra. Therefore, perforations 20 have been provided in the channel-shaped body 14 so that in its indwelling configuration in the prostatic urethra, the prosthetic device 10 does not block the flow of secretions from these little ducts.

Referring now to Figures 5 to 7, there is illustrated a method of implanting the prosthetic device 10 in the prostatic urethra.

The prostate generally is indicated by the reference numeral 30. The urinary bladder 32 is partially shown. The prostatic urethra 34 traverses the prostrate 30. The prostatic urethra 34 receives the ejaculatory duct 36 as well as the little prostatic ducts (not shown).

An instrument generally indicated by the reference numeral 40 is specially designed for the purpose of introducing the prosthetic device 10 in the prostatic urethra 34.

The instrument 40 comprises a set of three catheters 42, 44 and 46. The catheter 46 is a Foley's catheter. The catheters 42 and 44 are of physiologically acceptable material such as stainless steel or a polymer.

The diameter of catheter 44 is smaller than that of catheter 42. Thereby catheter 44 can be slidably displaced in the catheter 42. The inner diameter of the catheter 44 permits insertion of the prosthetic device 10 at one end of the catheter 44 as seen in Figure 5. As particularly seen in Figure 5, the tapering end 28 of the prosthetic device 10 is made to face inwards in the catheter 42. The catheter 44 is then inserted into the catheter 42 so that the end of catheter 44 abuts the prosthetic device 10. The Foley's catheter 46 having an inflatable bulb 48 is then inserted through the catheter 44. The inherent resilience of the prosthetic device 10 holds it in place in the catheter 42.

The instrument 40 is lubricated and inserted through the penile end of the urethra until its prosthetic device-bearing end extends into the bladder. The Foley's catheter 46 is then pushed forward gently until the bulb 48 of the Foley's catheter

46 can be inflated in the bladder 32 in the normal way. The Foley's catheter is then retracted against the neck 38 of the bladder 32. The inflated bulb 48 now serves as a datum point for implanting the prosthetic device 10 in the prostatic urethra. The outer catheter 42 is extended until the prosthetic device 10 abuts the inflated bulb 48. Figure 5 illustrates this position. Then, the inner catheter 44 is held firm and the outer catheter 42 is retracted until the prosthetic device 10 is implanted in the prostatic urethra through its resilience. Figure 6 illustrates this position. Now, the bulb 48 of the Foley's catheter 46 is deflated and the Foley's catheter 46 is retracted from the bladder. Figure 7 illustrates this position of the instrument 40. The instrument 40 can now be retracted out of the urethra, after a cysto-urethroscopic examination of the implanted prosthetic device 10. Typically, the catheters 42 and 44 have flared ends 50 for facilitating insertion, retraction and withdrawal. The catheters 42 and 44 are graduated near their flared ends 50 for precisely implanting the prosthetic device 10 in the prostatic urethra.

As seen in Figure 7, the "open face" of the channel-shaped body 14 of the prosthetic device 10 faces the ejaculatory duct 36 in the region of the verumontanum. Therefore the prosthetic device 10 does not obstruct the normal flow of seminal fluid from the ejaculatory duct 36.

The serrations 16 allow the channel-shaped body 14 of the prosthetic device 10 to grip the inner wall of the prostatic urethra. The wedge shaped projections 18 basically serve the same purpose. Together, the serrations 16 and the wedge-shaped projections 18 prevent spasmodic migration of an indwelling prosthetic device 10.

Suitable materials for the prosthetic device 10 are physiologically acceptable elastomeric polymers, such as TEFLON or silicon elastomers. Also, the channel-shaped body 14 of the prosthetic device can be lacquered with a coating of a vulcanized silicon elastomer.

CLAIMS

1. A prosthetic device comprising a physiologically acceptable, perforated, resilient body, which is channel-shaped in use, the inherent resilience of the body in its channel-shaped configuration, permitting the lumen of a prostatic urethra being kept open, when the body is left indwelling in the prostatic urethra.

2. A prosthetic device as claimed in Claim 1, in which the body is of an elastomeric polymer.

3. A prosthetic device as claimed in Claim 1 or Claim 2, in which the body is lacquered with a coating of a vulcanized silicon elastomer.

4. A prosthetic device as claimed in any one of the preceding claims, in which the body, in its channel-shaped configuration, has a horse shoe shaped end profile.

5. A prosthetic device as claimed in any one of the preceding claims, in which the body is provided with anchoring formations.

6. A prosthetic device as claimed in Claim 5, in which the anchoring formations include serrations on the edge of the body.

7. A prosthetic device as claimed in Claim 5 or Claim 6, in which the anchoring formations include wedge-shaped projections on the surface of the body intended to be in contact with the inner wall of the prostatic urethra.

8. A prosthetic device as claimed in any one of the preceding claims, in which the body is a planar tongue shaped element, which can be deformed into its in use, channel-shaped configuration.

9. A prosthetic device as described herein with reference to, and as illustrated in the accompanying drawings.